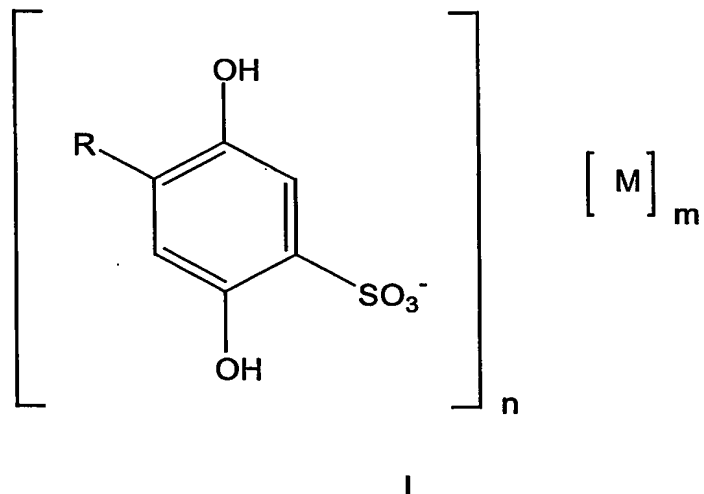


**Claims:****1. Active substance combination comprising**

(A) at least one 2,5-dihydroxybenzenesulfonic compound of general formula I,



wherein

R represents H or  $\text{SO}_3^-$ ,

M represents at least one cation,

n represents 1 or 2,

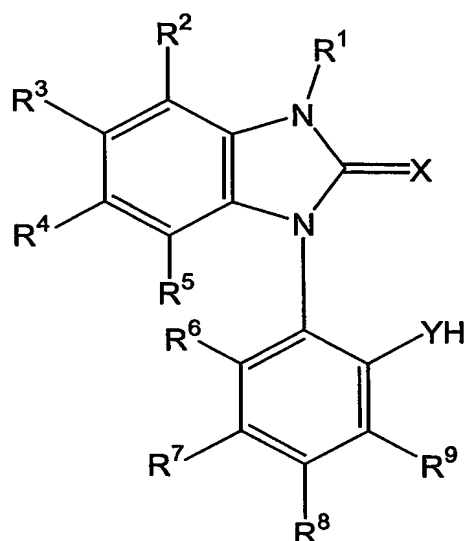
m represents 1 or 2,

optionally in form of a pharmaceutically acceptable solvate, and

(B) at least one potassium ion ( $\text{K}^+$ ) channel modulator.

2. Active substance combination according to claim 1, characterised in that the cation(s) M is (are) selected from the group consisting of  $\text{Ca}^{2+}$ ,  $\text{Mg}^{2+}$ ,  $\text{Na}^+$ ,  $\text{K}^+$  and  $[\text{NH}_{4-x}\text{R}_x]^+$ , whereby x is 0, 1, 2, 3 or 4 and R represents a branched or unbranched  $\text{C}_{1-4}$ -alkyl-radical that may be the same or different for  $x > 1$ .
3. Active substance combination according to claim 1 or 2, characterized in that the compound of general formula I is calcium 2,5-dihydroxybenzenesulfonate (calcium dobesilate).
4. Active substance combination according to claim 1 or 2, characterized in that the compound of general formula I is diethylamine 2,5-dihydroxybenzenesulfonate (ethamsylate).
5. Active substance combination according to claim 1 or 2, characterized in that the compound of general formula I is bis(diethylamine)-2,5-dihydroxybenzene-1,4-disulfonate (persilate).
6. Active substance combination according to one or more of claims 1-5, characterized in that the modulator of component (B) is a  $\text{K}^+$  channel opener.

7. Active substance combination according to claim 6, characterized in that the  $K^+$  channel opener is selected from the group consisting of benzimidazole derivatives of general formula I,



I,

wherein

X represents O, S or NCN,

Y represents O or S,

$R^1$  represents hydrogen,  $NH_2$  or branched or unbranched  $C_{1-6}$ -alkyl,

$R^2$ ,  $R^3$ ,  $R^4$ ,  $R^5$  are each independently selected from the group consisting of hydrogen, halogen,  $CF_3$ ,  $NO_2$ ,  $NH_2$ , OH,  $C_{1-6}$ -alkoxy,  $C(=O)$ -phenyl or  $SO_2NR^A R^B$ , wherein  $R^A$  and  $R^B$ , identical or different, represent H or  $C_{1-6}$ -alkyl,

$R^6$  represents hydrogen or  $NO_2$ ,

$R^7$  represents hydrogen, halogen, phenyl,  $CF_3$  or  $NO_2$ , or

R<sup>8</sup> represents hydrogen or NO<sub>2</sub>,

or

R<sup>6</sup> and R<sup>7</sup> or R<sup>7</sup> and R<sup>8</sup> together with the two bridging carbon atoms from the phenyl ring form a C<sub>4-7</sub> carbocyclic ring, which may be saturated, unsaturated or aromatic,

R<sup>9</sup> is hydrogen, halogen, NO<sub>2</sub> or SO<sub>2</sub>NR<sup>A</sup>R<sup>B</sup>, wherein R<sup>A</sup> and R<sup>B</sup>, identical or different represent hydrogen or C<sub>1-6</sub>-alkyl,

optionally in the form of a corresponding salt, or a corresponding solvate thereof, preferably 1-[2-Hydroxy-5-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-1,3-dihydro-2H-benzimidazol-2-one (NS1619), 6-Amino-1,2-dihydro-1-hydroxy-2-imino-4-piperidinopyrimidine (minoxidil), (R)-(-)-2-[4-(4-Methyl-6-oxo-1,4,5,6,-tetrahydropyridazin-3-yl)phenylhydrazono]propanedinitrile (levosimendan), N-[2-Amino-4-(4-fluorobenzylamino)phenyl]carbamic acid ethyl ester (retigabine), (-)-3-[5-oxo-2-(trifluoromethyl)-1,4,5,6,7,8-hexahydroquinolin-4(S)-yl]benzonitrile (ZD-0947), 2-Amino-5-(2-fluorophenyl)-4-methyl-1H-pyrrole-3-carbonitrile (NS-8), (3S, 4R)-3-Hydroxy-2,2-dimethyl-4-(2-oxopiperidin-1-yl)-N-phenyl-1-benzopyran-6-sulfonamide (KCO-912), (6-Chloro-3-(1-methylcyclopropylamino)-4H-thieno[3,2-e][1,2,4]thiadiazine-1,1-dioxide (NN-414), ABT-598, iptakalim hydrochloride, pinacidil, cromakalin, levcromakalin, aprikalim, N-(2-Hydroxyethyl)pyridine-3-carboxamide nitrate ester (nicorandil), (±)-(5-chloro-2-methoxyphenyl)-1,3-dihydro-3-fluoro-6-(trifluoromethyl)-2H-indol-2-one and ((3S)-(+)-(5-chloro-2-methoxyphenyl)-1,3-dihydro-3-fluoro-6-(trifluoromethyl)-2H-indol-2-one (BMS-204352), preferably from the group consisting of pinacidil and NS1619.

8. Active substance combination according to any one of claims 1 to 7, characterized in that it comprises component (A) in an amount of 0.1 µM to 100 µM, more preferably 1 µM to 10 µM.

9. Active substance combination according to claims 1 to 8, characterized in that it comprises component (B) in an amount of 0.001  $\mu\text{M}$  to 100  $\mu\text{M}$ , more preferably 0.01 to 10  $\mu\text{M}$ .
10. Medicament comprising an active substance combination according to any one of claims 1 to 9 and optionally at least one further active substance and/or optionally at least one auxiliary.
11. Medicament according to claim 10 for the prophylaxis and/or treatment of male sexual dysfunction, preferably erectile dysfunction, female sexual dysfunction, hypertension, type I diabetes mellitus, type II diabetes mellitus, hypercholesterolemia, bladder instability, urinary incontinence, asthma, ischemic injury, ischemic insufficiency to the brain, cardiovascular diseases, preterm labor or for stopping labor preparatory to Caesarean delivery, alopecias, epilepsy, gastrointestinal disorders including ulcers and dyspepsia, spasms, preferably gastrointestinal spasms, inflammatory diseases, preferably gastrointestinal inflammation, and/or cancer.
12. Use of an active substance combination according to any one of claims 1 to 9 for the manufacture of a medicament for the prophylaxis and/or treatment of male sexual dysfunction, preferably erectile dysfunction.
13. Use of an active substance combination according to any one of claims 1 to 9 for the manufacture of a medicament for the prophylaxis and/or treatment of female sexual dysfunction.
14. Use of an active substance combination according to any one of claims 1 to 9 for the manufacture of a medicament for the prophylaxis and/or treatment of hypertension.
15. Use of an active substance combination according to any one of claims 1 to 9 for the manufacture of a medicament for the prophylaxis and/or treatment of type I diabetes mellitus and/or type II diabetes mellitus.

16. Use of an active substance combination according to any one of claims 1 to 9 for the manufacture of a medicament for the prophylaxis and/or treatment of hypercholesterolemia.
17. Use of an active substance combination according to any one of claims 1 to 9 for the manufacture of a medicament for the prophylaxis and/or treatment of bladder instability.
18. Use of an active substance combination according to any one of claims 1 to 9 for the manufacture of a medicament for the prophylaxis and/or treatment of urinary incontinence.
19. Use of an active substance combination according to any one of claims 1 to 9 for the manufacture of a medicament for the prophylaxis and/or treatment of asthma.
20. Use of an active substance combination according to any one of claims 1 to 9 for the manufacture of a medicament for the prophylaxis and/or treatment of ischemic injury.
21. Use of an active substance combination according to any one of claims 1 to 9 for the manufacture of a medicament for the prophylaxis and/or treatment of ischemic insufficiency to the brain.
22. Use of an active substance combination according to any one of claims 1 to 9 for the manufacture of a medicament for the prophylaxis and/or treatment of cardiovascular diseases.
23. Use of an active substance combination according to any one of claims 1 to 9 for the manufacture of a medicament for the prophylaxis and/or treatment of preterm labor.
24. Use of an active substance combination according to any one of claims 1 to 9 for the manufacture of a medicament for stopping labor preparatory to Caesarean delivery.

25. Use of an active substance combination according to any one of claims 1 to 9 for the manufacture of a medicament for the prophylaxis and/or treatment of alopecias.
26. Use of an active substance combination according to any one of claims 1 to 9 for the manufacture of a medicament for the prophylaxis and/or treatment of epilepsy.
27. Use of an active substance combination according to any one of claims 1 to 9 for the manufacture of a medicament for the prophylaxis and/or treatment of gastrointestinal disorders including ulcers and dyspepsia.
28. Use of an active substance combination according to any one of claims 1 to 9 for the manufacture of a medicament for the prophylaxis and/or treatment of gastrointestinal spasms.
29. Use of an active substance combination according to any one of claims 1 to 9 for the manufacture of a medicament for the prophylaxis and/or treatment of inflammatory diseases.
30. Use of an active substance combination according to any one of claims 1 to 9 for the manufacture of a medicament for the prophylaxis and/or treatment of gastrointestinal inflammation.
31. Use of an active substance combination according to any one of claims 1 to 9 for the manufacture of a medicament for the prophylaxis and/or treatment of cancer.
32. Pharmaceutical formulation comprising an active substance combination according to any one of claims 1 to 9 and optionally at least one further active substance and/or optionally at least one auxiliary.
33. Pharmaceutical formulation according to claim 32, characterized in that it is suitable for oral administration.

34. Pharmaceutical formulation according to claim 33, characterized in that the medicament is in the form of a tablet, a capsule or a suspension.
35. Pharmaceutical formulation according to claim 33, characterized in that is in form of multiparticulates, preferably pellets or granules, optionally compressed into a tablet, filled into a capsule or suspended in a suitable liquid.
36. Pharmaceutical formulation according to any one of claims 32 to 35, characterized in that it comprises component (A) and/or component (B) at least partially in a sustained-release form.
37. Pharmaceutical formulation according to claim 36, characterized in that it has at least one coating or matrix comprising at least one sustained-release material.
38. Pharmaceutical formulation according to claim 37, characterized in that the sustained-release material is based on an optionally modified, water-insoluble, natural, semisynthetic or synthetic polymer, or a natural, semisynthetic or synthetic wax or fat or fatty alcohol or fatty acid, or on a mixture of at least two of these afore mentioned components.
39. Pharmaceutical formulation according to claim 38, characterized in that the water-insoluble polymer is based on an acrylic resin, which is preferably selected from the group of poly(meth)acrylates, poly(C<sub>1-4</sub>)dialkylamino(C<sub>1-4</sub>)alkyl (meth)acrylates and/or copolymers thereof or a mixture of at least two of the afore-mentioned polymers.
40. Pharmaceutical formulation according to claim 38, characterized in that the water-insoluble polymers are cellulose derivatives, preferably alkyl cellulose and particularly preferably ethyl cellulose, or cellulose esters.
41. Pharmaceutical formulation according to claim 38, characterized in that the wax is carnauba wax, beeswax, glycerol monostearate, glycerol monobehenate,



glycerol ditripalmitostearate, microcrystalline wax or a mixture of at least two of these components.

42. Pharmaceutical formulation according to any one of claims 38-41, characterized in that the polymers have been used in combination with one or more plasticizers.
43. Pharmaceutical formulation according to any one of claims 32 to 42, characterized in that it comprises at least one enteric coating.
44. Pharmaceutical formulation according to any one of claims 32 to 43, characterized in that it comprises at least one immediate-release coating comprising component (A) and/or component (B).
45. Pharmaceutical formulation according to claim 32 suitable for parenteral administration, preferably intravenous administration.